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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,001	05/30/2001	Mitsuharu Ono	ASAHI-1-PC-1	4787

466 7590 03/05/2003

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
701,011	ONO et al
Examiner	**Group Art Unit**
STANDISH	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 11/13/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-34 is/are pending in the application.

Of the above claim(s) 1, 6-10, 14-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 2-4, 11-13, 29-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1-34 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The claims pending are 1-34.

Claims 2-4, 11-13 and 29-34 are examined.

Applicant's election with traverse of Group II (original claims 2-4 and newly-added, dependent claims 29-34) in Paper No. 10 (filed 11/13/02)is acknowledged. The traversal is on the ground(s) that the International examiner did not find lack of Unity of Invention. This is not found persuasive because the International examiner found claims that were unpatentable over the prior art. These claims thus provide no contribution over the prior art as required by PCT Rule 13.1 that defines unity of invention. Further even without this finding of prior art, the claims pertaining to anti-CD4 and to anti-CD34 antibodies and their uses would form two Inventions, since these antibodies have different binding specificities. To search for and cite the art used further below in the prior art rejection places a sufficient burden on the examiner, and it would be an undue burden to search more.

The requirement is still deemed proper and is therefore made FINAL.

Upon reconsideration, claims 11-13 of Group V have been rejoined with Group II.

The disclosure is objected to because of the following informalities: In the replacement paragraph beginning at page 24, line 4, in the penultimate line thereof, applicant is required to identify the residue numbers, of SEQ ID NO: 9 of which the recited sequence is a "piece". See MPEP 2424.03.

Appropriate correction is required.

Claims 2-4, 11-13 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are unclear by reciting "a device for separating CD4-positive cells using an antibody" "because they do not define the "device" in terms of any structural features other than the antibody and do not set forth the structural relationship of the antibody to any other component of the "device."

In claim 2, 30, 32, and 34 the Markush group of antibodies is indefinite without recitation of --the group consisting of-- after "selected from".

In claim 2 "combinations thereof" is unclear. Does this mean that the device uses one type of antibody, which is a "combination" of a chimeric antibody and a single chain (SC) antibody, or does this mean that the devices uses a "combination" of two antibodies, one being chimeric and one being SC? Alternatively, if "combinations thereof" modifies "CD4 molecules", it is not clear how such "combinations" are constituted.

Claims 11-13 set forth an incomplete method of separating or detecting without recitation of any steps or conclusions drawn from the steps - e.g. There is no step of contacting the cells with antibody, no step of separating, no step of detecting anything (such as a signal), and no step of relating what is detected to the presence of CD4+cells.

In claim 32 the Markush group of antibodies improperly recites more members than are recited in base claim 3, which only recites "chimera antibody."

In like manner, in claim 34, the Markush group of antibodies contains a greater number of members than are recited in base claim 4, which only recites "single chain antibody."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorman et al. (WO 92/05274).

Gorman et al. show anti-CD4 antibodies having CDR regions from a rodent antibody grafted into a human framework. Such antbodies fall within the scope of "chimera" antibodies, as defined by applicant at page 21. At pages 23 and 28 Gorman et al. evaluate binding of such anti-CD4 antibodies by fluorescence activated cell sorting.(FACS). The FACS method involves both cell separation and detection of labeled cells. Claim 2 is properly anticipated by the grafted antibody of Gorman et al. is capable of separating cells in a FACS method; this is sufficient to reject claim 2, which is devoid of reciting any structural features other than the antibody per se. Claim 11 is properly anticipated by the FACS method of Gorman et al. because this

labels CD4+ cells; this is sufficient to reject claim 11, which is devoid of any proper method steps.

Claims 2 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Burkly et al. (5,871,732).

Burkly et al. teach anti-CD4- antibody homologs. Such homologs include chimeric and humanized antibodies to CD4. See col. 4, lines 58-61; col. 7, lines 44 - 58; col. 16, line 53 - col. 17, line 54. They teach that such antibodies can be bound to "detectable agents"; see col. 5, lines 23-28; col. 18, lines 24-57. The use of such in a method of detecting CD4-cells would have been immediately apparent; hence claim 11 is anticipated. Also Burkly et al. teach immunoassays in which the anti-CD4 antibody homologs are screened --e.g. by FACS analysis; see col. 10, lines 19-42. As noted supra for Gorman et al. Such FACS analysis involves both cell separation and cell detection; hence claims 2 and 11 are both anticipated. Also as noted supra claim 2 fails to set forth any device elements other than an antibody. Thus the anti-CD4 antibody homologue of Burkly et al., when conjugated to a fluorochrome or to biotin (col. 18, lines 42-45 and 56) properly anticipate claim 2, because such conjugates could be used in a separation method (e.g. FACS or with avidin coated particles).

Claims 2-3 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinton et al. (EP 0,365,209).

Hinton et al. disclose chimeric and mosaic (humanized) vesion of the anti-CD4 antibody, anti Leu-3a. This is considered to anticipate instant claim 2 because, as noted supra for Gorman et al. and Berkly et al. , claim 2 is so devoid of any apparatus structural limitations that the mere antibody anticipates.

Hinton et al. disclose useof the antibodies in diagnostics (col. 3, lines 43+). Since instant claim 11 is devoid of any detection steps, the teachings of Hinton et al. are sufficient to anticipate.

Regarding claims 3 and 12, the V-kappa chain sequence shown by Hinton et al. in Figure 2 shows instant SEQ ID NOS: 4-6; see boxed sequences. Likewise the H-chain sequence shown in Figure 3 shows instant SEQ ID NOS: 1-3; see boxed sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan , can be reached on (703)308-3973 . The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunder:jmr

February 25, 2003

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644